

## Accreditation of proficiency testing providers

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### Scope:

This policy sets out requirements for the accreditation procedure for proficiency testing providers (PT providers) on the basis of DIN EN ISO/IEC 17011. It also specifies, where necessary, the general requirements of DIN EN ISO 17043 for PT providers.

It applies to PT providers with or without their own testing or calibration laboratory.

Additional sectoral rules setting out requirements for the accreditation procedure for PT providers or requirements for PT providers may also apply.

**Date of confirmation by the Accreditation Advisory Board: 25.04.2020**

Pursuant to Section 2 in conjunction with Section 3 (9) Federal Act on Gender Equality, Section 4 (3) Federal Act on Gender Equality is not directly applicable to DAkkS. In the interest of good readability, the generic masculine is also used for function descriptions in this document, so far as a concrete designation by natural gender is not possible in any meaningful way and natural gender is either unimportant or male and female persons are meant equally.

DAkkS rules and other technical specifications must be easily readable and must therefore contain no slashes, which excludes the use of the internal / and duplicate designations (concerning admissibility, see Section 115 Manual for Drafting Legislation).

Also applicable are the further requirements of DIN 820-2:2012-12 Standardization – Part 2: Presentation of documents (ISO/IEC Directives – Part 2:2011) for the formulation of technical specifications.

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## **I Requirements for the accreditation procedure**

This section specifies the requirements of DIN EN ISO/IEC 17011 for the accreditation of PT providers. The numbering within this section follows the numbering of DIN EN ISO/IEC 17011.

### **7.1 (DIN EN ISO/IEC 17011) Requirements for accreditation**

Subject-specific documents such as DIN 38402-45 must be taken into account also if this is indicated for technical reasons or required by law or normative documents.

### **7.2 (DIN EN ISO/IEC 17011) Application for accreditation**

7.2.1 The basis for the assessment is the table provided by DAkkS in the annex to the accreditation application specific to PT providers (72 FB 005.37). This must be completed by the PT provider and made available with the application. With the documents to be submitted, a further table is requested (72 FB 004.5\_A1\_e\_list of PT's.xlsx), in which PT providers enter which proficiency tests have been carried out in which areas since when and how often. The latter table allows the auditors to assess the experience of the PT provider in conducting proficiency tests in the areas covered by the application. Depending on the level of experience in conducting proficiency tests, either individual selected proficiency test or areas which may include several different proficiency tests can be accredited.

### **7.4 (DIN EN ISO/IEC 17011) Preparation for the assessment**

7.4.1 The assessment team must include at least one technical assessor/expert (FB<sub>stat</sub>) with practical experience in interlaboratory comparison statistics who, together with the other technical assessors, assesses the statistical procedures for homogeneity and stability testing and for the statistical evaluation of proficiency tests and evaluation of the performance of participants.

For PT providers of calibration services, the areas covered by the application are usually assessed by assessors for calibration laboratories with additional training for DIN EN ISO/IEC 17043.

## 7.6 (DIN EN ISO/IEC 17011) Assessment

7.6.1 The objective of the assessment is to verify that the PT provider has the competence to plan proficiency tests, to evaluate the performance of participants and to authorise the interlaboratory comparison reports under its own responsibility, and where applicable to assess the competence of subcontractors. During each scheduled assessment, at least one process for a proficiency test that was performed must be assessed exemplarily for the areas to be assessed. For each process assessed, the entire process from planning of the proficiency test to dispatch of the final reports to the participants and, where necessary, any follow-up work must be assessed with regard to the competence of the personnel involved. Particular emphasis is given to the planning and implementation of the proficiency test, determination of the assigned values and the selection criteria, as well as statistical analysis and authorisation of the results, the preparation of reports and the competence of the personnel involved. The assessment must include a witness audit of parts of the practical conduct of a proficiency test.

PT providers who have not conducted proficiency tests prior to their application must have at least one proficiency test fully planned and prepared in each area in which they are seeking accreditation (see 72 FB 005.37). The assessment of competence is based on these proficiency test. The assessment of the suitability of statistical analyses must be carried out using sample data sets. For each area, an assessment must be carried out for the first organised Proficiency test during evaluation and report preparation. Accreditation is possible only after completion of a proficiency test for the areas covered by the application for accreditation.

Where subcontractors are used, appropriate evidence of the competence of subcontractors must be provided. During the assessment, the PT provider must be able to provide appropriate evidence of its competence to assess the suitability of subcontractors for the work subcontracted.

7.6.3 During the planning of the assessment, at least the following factors must be considered:

- Aspects of the standard which are of equal interest to all assessors must be jointly assessed. With respect to the topics of evaluation of the performance of participants (4.7.2), and for homogeneity and stability testing (4.4.3) and determination of the assigned values (4.4.5), a joint assessment or exchange between FB and FB<sub>stat</sub> are essential in order to enable assessment of whether the statistically determined data is applicable and fit for intended use. The extent of the assessment by the technical assessor for statistics (FB<sub>stat</sub>) depends on the number and complexity of the statistical procedures used and is determined by DAkKS for each individual case;
- On-site witness audits in which parts of the conduct of the proficiency test, such as sample preparation, splitting, packaging etc. are observed by the assessor or assessors. If no proficiency test is being performed at the time of the assessment, parts of the proficiency test can also be demonstrated;

- Verification of the competence of subcontractors by the PT provider and the associated documentation;
- Contracts with external personnel;
- Procedures for the use of advisory groups and the documentation of their activities;
- Assessment of non-accredited test methods if they are used for proficiency tests.  
However, an assessment of these requirements within the framework of the performance of proficiency tests is not equivalent to an accreditation as a testing laboratory in accordance with DIN EN ISO/IEC 17025. Documentation of the assessment of the test methods is by means of form 75 FB 002.1\_17025-2018\_e\_chl-report (sections 6 and 7), form 75 FB 008.1\_e\_sheet-general or the relevant sector-specific forms where applicable.

For PT providers for calibration services that meet the following conditions, the assessment may be simplified.

- Accreditation as a calibration laboratory for all measurands offered for the proficiency tests. The decisive factor is the accredited calibration scope including the smallest measurement uncertainties that can be specified;
- Exclusive use of reference values as assigned values in conjunction with  $E_n$  numbers;
- No subcontracting;
- Consignment of the same PT object (one or more) to several participants.

Simplification may include the following aspects:

- The assessment of statistics by a statistics assessor can be omitted;
- The areas covered by the application are assessed by the assessors for calibration laboratories with additional training for DIN EN ISO/IEC 17043;
- The assessment of the PT provider can be combined with the assessment of the calibration laboratory; the assessment duration must be extended accordingly.

Technical emphasis is given to the planning of proficiency tests and the specification and suitability of PT material, as well as the assessment of proficiency test and evaluation of the performance of participants.

## 7.7 (DIN EN ISO/IEC 17011) Accreditation decision-making

7.7.3 (i) For the decision-making process, the Accreditation Committee requires the following additional documents:

- The completed Excel table (72 FB 004.5\_A1\_e\_list of PT's);
- A completed form 75 FB 008.36a for each assessed proficiency test for testing laboratories and the on-site witness audit, and
- A completed form 75 FB 008.36b for each assessed proficiency test for calibration laboratories and the on-site witness audit;
- A completed Form 75 FB 008.36c for each statistical procedure assessed, and
- A completed form 75 FB 008.36d for each subcontractor assessed respectively.

## 7.8 (DIN EN ISO/IEC 17011) Accreditation information

7.8.3 e) The scope of accreditation is presented in tabular form based on the EA document EA-2/18. On the basis of the application, the scope of accreditation is determined together with the submitted Excel table (72 FB 004.5\_A1\_e\_list of PT's), which reflects the experience of the PT provider, and the results of the assessment. Depending on the level of experience in the organisation of proficiency tests, individual selected tests or areas which may include several different proficiency tests can be accredited. If the PT provider has carried out only a small number of proficiency tests to date, or if the assessment shows that there is little experience or limited technical competence in certain areas, only specific proficiency tests with a defined scope are accredited.

Where comprehensive experience and competence is available, the areas can be defined using more or less general information about the proficiency test item (PT item), e.g. the specification of a product group. Instead of individual parameters, parameter groups can be defined accordingly. In the defined areas, the PT provider may then also carry out proficiency tests with other PT items or attributes within the framework of accreditation without leaving the scope of accreditation. Examples to illustrate this are given in Annex 1.

This assumes that the evaluation methods are retained and that the test, calibration and analysis methods used for the new parameters or products added, including sample pretreatment, are not fundamentally different from those used in the accredited area. If however this is not the case, these proficiency tests are outside the scope of the accreditation.

PT providers accredited with variable scope must maintain an up-to-date list of the proficiency tests in the accredited area (content: name of proficiency test, PT item, parameter/measurand, year of performance), and must provide it to their customers and DAkkS upon request. This list is referenced in the annex to the accreditation certificate as follows:

“The proficiency test provider maintains an up-to-date list of proficiency tests in the accredited area.”

## II Specification of requirements of DIN EN ISO/IEC 17043

This section specifies the requirements of DIN EN ISO/IEC 17043 in greater detail. The numbering within this section follows the numbering of DIN EN ISO/IEC 17043.

### 4.2 (DIN EN ISO/IEC 17043) Personnel

4.2.3 If external personnel are used, they must be contractually bound (permanently or project-based). The contracts must contain at least the following:

- Description of the activity commissioned (area and type of activity);
- Duration of the activity commissioned;
- Arrangements for the protection of confidentiality and impartiality;
- Integration into the quality management system and commitment to adhere to it;
- Arrangements concerning training and the documentation of the required competence.

### 4.4 (DIN EN ISO/IEC 17043) Design of proficiency testing schemes

4.4.1.4 If the PT provider makes use of additional expertise, the following documents must be kept available:

- List of experts employed in the individual areas in which proficiency tests are organised;
- Information on the technical knowledge of the experts.

Arrangements and records (e.g. minutes of meetings, telephone notes) must be in place to show how and to what extent the experts are employed.

### 4.7 (DIN EN ISO/IEC 17043) Data analysis and evaluation of proficiency testing scheme results

4.7.1.1 For the validation of equipment and software, a documented receiving inspection with test data sets for functionality or proof that correct results have been obtained in accordance with the intended purpose must be provided.

### 4.8 (DIN EN ISO/IEC 17043) Reports

4.8.2.i) The requirement is met when all information regarding the PT items is included in the report required by a customer to interpret the proficiency testing results.

#### **4.9 (DIN EN ISO/IEC 17043) Communication with participants**

4.9.5 If, in addition to the proficiency test report, individual certificates of participation or performance are to be issued, they must contain at least the following information in order to avoid misinterpretation:

- Subject and scope of the proficiency tests (including designation of the parameters tested);
- Name and address of the PT provider;
- Name of participant and participant's code number;
- Number of the proficiency test;
- Reference to the final report;
- Number of pages and total number of pages of the certificate of participation on each page;
- Name, function and signature of the authorised signatory;
- Date of implementation of the proficiency testing scheme;
- Criteria for the assessment, e.g. 80% of results submitted passed;
- Results of the participant.

If an assessment such as “passed successfully” is made, the basis for the assessment must be stated on the certificate.

If an electronic signature procedure is used, the PT provider must make arrangements to ensure that it meets the functional and security requirements to the same extent as a conventional signature. This is especially true for unambiguous, reproducible and tamper-proof linkage of the electronic signature to the approving person.

#### **5.4 (DIN EN ISO/IEC 17043) Review of requests, tenders and contracts**

5.4.1 The following cases must be distinguished:

- Contract to carry out a proficiency test by a customer. In these cases, the requirements of section 5.4 must be applied.
- Participation of laboratories or inspection bodies in repeated proficiency tests carried out by the PT provider. The requirements of section 5.4 must be met in this respect that the customer is to be informed comprehensively enough to enable him to decide upon the proficiency test is suitable for his purposes.

## 5.5 (DIN EN ISO/IEC 17043) Subcontracting services

5.5.1 The PT provider must have the competence to assess subcontractors and evaluate the results of subcontracting. For each proficiency test, it must be clear which activities are subcontracted.

Fulfilment of the relevant requirements of the applicable standards by the subcontractor and of the competence of the subcontractor must be proven by the PT provider with informative records. For testing, calibration, analysis and inspection services, the requirements can be fulfilled as follows:

- For testing, calibration and inspection by a subcontractor, an accreditation in accordance with a standard in the 17000 series or, in the case of medical examinations, an accreditation in accordance with DIN EN ISO 15189 is sufficient for the methods used. Participation in the CIPM MRA and participation in key comparisons are considered valid as proof.
- Alternatively, the PT provider can use an on-site audit carried out by a competent auditor and documented in writing to provide evidence that the relevant requirements of the applicable standards in the 17000 series or DIN EN ISO 15189 as well as other applicable requirements are fulfilled for the subcontracted work.

These audits must be conducted regularly.

Competent and comprehensive conduct of the audit must be clearly evident from the audit records.

For the in-company transfer of work covered by DIN EN ISO/IEC 17043, the internal contractor must be included in the PT provider's quality system or, if this is not possible, treated as a subcontractor.

The production of PT items is considered to be subcontracting only if tests relating to content, homogeneity and stability or other required characteristics are included in the manufacturing process.

## Bibliography

EA-2/18: INF 2015-10	Guidelines for accreditation bodies on the contents of the scopes of accreditation for proficiency testing providers
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## Annex 1 to 7.8 (DIN EN ISO/IEC 17011) Accreditation information (informative)

### Examples of the design of the certificate annex in accordance with section 7.8 with explanations:

The first four columns in the table describe the scope of accreditation and are obligatory, as is the location column, if the PT provider operates at multiple locations. If a large number of different proficiency tests are offered in one testing area, a representative selection must be entered in the column “Name of PT scheme”.

For PT providers for the area of calibration, the table contains an additional column in which side conditions can be defined.

The following examples are designed to show how the choice of terminology can make the accredited area of PT providers more or less variable. The names of the PT schemes here are chosen at random.

Example of a scope of accreditation without possible variations within the accreditation.

Test area	Proficiency test item	Measurands/ test parameters	Name of PT scheme	Location
Chemical testing	Drinking water	Lead, cadmium, nickel	DW-PT	Berlin

In this case, the accreditation for proficiency tests with lead, nickel and cadmium applies exclusively to drinking water.

Example of a scope of accreditation with possible variations for the PT items within the accreditation.

Test area	Proficiency test item	Measurands/test parameters	Name of PT scheme	Location
Chemical testing	Water	Lead, cadmium, nickel	Water PT	Berlin

An accreditation is hereby issued for proficiency tests for the determination of lead, cadmium, nickel in all waters from ultrapure water to sea water and waste water.

The PT item “water” can be limited for example to natural water, fresh water, industrial water and waste water, raw and drinking water.

Example of a scope of accreditation with possible variations for the test parameters within the accreditation.

Test area	Proficiency test item	Measurands/test parameters	Name of PT scheme	Location
Chemical testing	Drinking water	Metals	DW-PT	Berlin

The accredited area covers proficiency tests for the determination of all metals in the periodic table in drinking water.

The test parameter “metals” can be limited for example to heavy metals, trace metals, alkali metals and alkaline earth metals or “metals in accordance with TrinkwV”.

Optionally, possible variations for products and test parameters can also be granted in combination.

Example of the presentation of the scope of accreditation of a PT provider in the area of calibration.

Subject field	Measurand/calibration item	Conditions	Proficiency testing scheme	Location (if required)
Electrical measurands Direct current and low frequency			Proficiency testing schemes are organised on request.	
AC voltage	AC voltage <b>Low variability:</b> Standard Fluke 5790A  <b>High variability:</b> Voltage meters  <b>Low variability:</b> High-voltage sources, High-voltage dividers Square-wave voltage Delta voltage  <b>High variability:</b> Voltage sources			
	Frequency response $F_{U_{z_0}}$ of the output voltage of generators	based on 1 kHz at the nominal impedance $Z_0 = 50 \Omega$		
	Transfer difference of the incident voltage $\delta_{\text{ein},1k}$ AC voltage meters with 50 $\Omega$ input impedance	based on 1 kHz		